510(K) Summary of Safety and Effectiveness for the

ADVIA® Centaur Calibrator 30

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. 510(K) Number: k100293

B. Date of Preparation: January 20, 2010

C. Proprietary and Established Names:

MAR 19 2010

ADVIA Centaur systems, ADVIA Centaur Calibrator 30

D. Applicant:

Siemens Healthcare Diagnostics Inc., 511 Benedict Ave, Tarrytown, NY 10591

Ernest Joseph, Senior Regulatory Specialist

Office: (914) 524-2431 Fax: (914) 524-2500

E. Regulatory Information:

ADVIA Centaur systems, ADVIA Centaur Calibrator 30

1. Regulation section: 21 CFR § 862.1150 Calibrator, Secondary
2. Classification: Class II
3. Product Code: JIT
4. Panel: Clinical Chemistry

F. Predicate Device:

The ADVIA Centaur Calibrator 30 is substantially equivalent to the ADVIA Centaur Calibrator E which was cleared under K932715/K954697

G. Device Description:

The ADVIA Centaur® Calibrator 30 is a 2 level human plasma based solutions containing varying concentrations of Estradiol in charcoal stripped defibrinated human plasma, 0.1% Sodium azide and preservatives. The Estradiol calibrators have expected values of 35 and 2500 pg/mL.

The Cal 30 (2.0 mL/vial) is lyophilized. Storage for lyophilized cal is at 2 - 8°C until expiration date specified on label, reconstituted calibrator storage is at 2-8°C up to 14 days, and on board is up to 4 hours.

Statement of Intended Use:

For *in vitro* diagnostic use in calibrating the following assays using the ADVIA Centaur® systems.

Enhanced Estradiol (eE2)

Comparison to the Predicate Device:

Similarities and Differences between the devices and the predicate are shown below:

Similarities

	Device	Predicate
Item	ADVIA Centaur® Calibrator 30	ADVIA Centaur® Calibrator E K 932715/K954697
Number of Levels	2	2
Form	Lyophilized	Lyophilized
Matrix	charcoal stripped defibrinated plasma	charcoal stripped defibrinated plasma
Intended Use	For *in vitro* diagnostic use	For *in vitro* diagnostic use
Storage (Lyophilized and open vial)	2°C to 8°C	2°C to 8°C
Stability	**Unopened** – until expiration date on the vial label **Opened** - 14 days or **On-board** - 4 hours	**Unopened** – until expiration date on the vial label **Opened** - 14 days or **On-board** - 4 hours

	Device	Predicate
Item	ADVIA Centaur® Calibrator 30	ADVIA Centaur® Calibrator E K 932715/ K954697
Constituents	Estradiol, Testosterone, Progesterone and Cortisol.	Estradiol, Testosterone, Progesterone and Cortisol.

Differences

	Device	Predicate
Item	ADVIA Centaur® Calibrator 30	ADVIA Centaur® Calibrator E K 932715/ K954697
Intended use	For use in calibrating the following assays using the ADVIA Centaur® systems: Enhanced Estradiol (eE2)	For use in calibrating the following assays using the ADVIA Centaur® systems: Estradiol, Testosterone, Progesterone and Cortisol
Analyte Values	Enhanced Estradiol (eE2)	Estradiol,.Testosterone, Progesterone and Cortisol
Targeted Concentration of levels	Low = 35 pg/mL High = 2500 pg/mL	Low = 120 pg/mL High = 1450 pg/mL

Performance:

The traceability, value assignment, and stability of the ADVIA Centaur® Calibrator 30 have been validated following procedures of Siemens Healthcare Diagnostics.

Conclusions:

The ADVIA Centaur® Calibrator 30 is substantially equivalent to previously cleared ADVIA Centaur Calibrator E.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

MAR 19 2010

Siemens Healthcare Diagnostics Inc.
c/o Ernest Joseph
Senior Regulatory Specialist
511 Benedict Avenue
Tarrytown, NY 10591

Re: k100293
Trade Name: ADVIA Centaur Calibrator 30
Regulation Number: 21 CFR §862.1150
Regulation Name: Calibrator, Secondary
Regulatory Class: Class II
Product Codes: JIT
Dated: January 31, 2010
Received: February 2, 2010

Dear Mr. Joseph:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K100293
Device Name: ADVIA Centaur Calibrator 30
Indication for Use:

For in vitro diagnostic use in calibrating the following assays using ADVIA Centaur Systems.

Enhanced Estradiol (eE2)

ADVIA Centaur calibrator 30 is a device intended for medical purposes for use in Estradiol Assay to establish points of reference that are used in the determination of values in the measurement of Estradiol in human serum, Heparinized and EDTA Plasma.

Prescription Use X And/Or Over the Counter Use_____

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K100293